

Current claim summary

1- 48 (canceled)

49. (currently amended) A controlled release dosage form, comprising:

(a) a core, having a drug layer composition and a sweller layer composition in a bi-layer geometry, comprising an osmotic agent contained in the sweller layer composition and, contained in the drug layer composition, a low solubility drug in the form of a solid dispersion of said drug in a dispersion polymer, ~~at least a major portion wherein~~ substantially all of said drug ~~being~~ is amorphous, and wherein said drug in said solid dispersion exhibits amorphous character in at least one of x-ray diffraction analysis or differential scanning calorimetry; and

(b) a water-permeable coating around said core having at least one delivery port therein, said coating controlling the influx of water to said core from an aqueous environment of use to cause extrusion of at least a portion of said core through said at least one delivery port to said aqueous environment of use, said coating being non-dissolving and non-eroding during release of said drug;

wherein said dispersion polymer is selected from the group consisting of hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose acetate succinate, hydroxypropylmethylcellulose acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, and carboxymethylethylcellulose.

50. (canceled)

51. (previously presented) The dosage form of claim 49 wherein said solid dispersion is homogeneous.

52. (previously presented) The dosage form of claim 49 further comprising an osmotically effective solute.

53. (canceled)

54. (canceled)

55. (previously presented) The dosage form of claim 49 wherein said osmotic agent comprises a water-swellaable hydrophilic polymer that is separate from said dispersion polymer.

56. (previously presented) The dosage form of claim 55 wherein said water-swellable hydrophilic polymer is selected from the group consisting of hydrophilic vinyl and acrylic polymers, polysaccharide alginates, poly(ethylene oxide), polyethylene glycol, polypropylene glycol, poly(2-hydroxyethyl methacrylate), poly(acrylic) acid, poly(methacrylic) acid, polyvinyl pyrrolidone, crosslinked polyvinyl pyrrolidone, polyvinyl alcohol, polyvinyl pyrrolidone/polyvinyl alcohol copolymers, vinyl acetate, hydrophilic polyurethanes containing large polyethylene oxide blocks, carrageenan, hydroxethyl-cellulose, hydroxypropylcellulose, hydroxypropylmethyl-cellulose, carboxymethylcellulose, carboxyethylcellulose, sodium alginate, polycarbophil, gelatin, xanthan gum, sodium croscarmellose, and sodium starch glycolate.

57. (previously presented) The dosage form of claim 49 wherein said solid dispersion is formed by spray-drying said low-solubility drug and said dispersion polymer together in a solvent.

58. (canceled)

59. (previously presented) The dosage form of claim 49 wherein said dispersion polymer is hydroxypropylmethyl cellulose acetate succinate.

60. (previously presented) The dosage form of claim 49 wherein said dosage form provides an AUC in a use environment that is at least 1.25-fold that of a control dosage form comprising an identical dosage form containing an equivalent quantity of undispersed drug.

61. (previously presented) The dosage form of claim 49 wherein said dosage form is dosed orally to a mammal, said dosage form provides an AUC in drug concentration in the blood that is at least 1.25-fold that of a control dosage form comprising an identical dosage form except containing an equivalent quantity of undispersed drug.

62. (previously presented) The dosage form of claim 49 wherein said drug is selected from the group consisting of an anti-hypertensive, and antianxiety agent, an anticlotting agent, a blood glucose-lowering agent, a decongestant, an antihistamine, an antitussive, an anti-inflammatory, an anti-atherosclerotic agent, an antipsychotic agent, a cognitive enhancer, a cholesterol-reducing agent, an antiobesity agent, an autoimmune disorders agent, a hypnotic agent, an anti-Parkinsonism agent, an antibiotic, an antiviral agent, an anti-impotence agent, an anti-neoplastic, a sedative, a barbituate, a nutritional agent, a

beta-blocker, an emetic, an anti-emetic, a diuretic, an anticoagulant, a cardiotonic, an androgen, a corticoid, an anabolic agent, an anti-depression agent, an anti-infective agent, a coronary vasodilator, a carbonic anhydrase inhibitor, an antifungal, an antiprotozoal, a gastrointestinal agent, a dopaminergic agent, an anti-Alzheimer's Disease agent, an anti-ulcer agent, a platelet inhibitor, and a glycogen phosphorylase inhibitor.

63-78 (canceled)